UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Norfolk Division

CUREVAC SE (f/k/a CUREVAC AG) and CUREVAC MANUFACTURING GMBH,

Plaintiffs,

v. **Civil Action No. 2:23-cv-222**

BIONTECH SE, BIONTECH MANUFACTURING GMBH, and PFIZER, INC.,

Defendants.

MEMORANDUM ORDER

Plaintiffs CureVac SE and CureVac Manufacturing GMBH ("CureVac") moved in Limine to preclude BioNTech from relying on specific prior art references constituting "the general background knowledge" of a person of ordinary skill in the art ("POSA") to prove obviousness with respect to all claimed patents, asserting that BioNTech violated a stipulation between the parties in disclosing such arguments. (ECF No. 627, at 1). Defendants BioNTech SE, BioNTech Manufacturing GMBH, and Pfizer, Inc. ("BioNTech"), respond that the obviousness inquiry requires the factfinder to consider the pre-existing general knowledge of a POSA, and that the stipulation allows BioNTech to rely on supporting references demonstrating this generalized knowledge. (ECF No. 690, at 1). As explained below, I agree that the stipulation does not preclude these arguments and therefore DENY CureVac's Motion in Limine No. 4, (ECF No. 626).

I. BACKGROUND

A. The Patents in Suit.

CureVac asserts infringement of seven U.S. patents divided among four patent families. The four families each derive from applications with varying priority dates, and cover different technology alleged to be practiced by the BioNTech COVID vaccine, Comirnaty®.

One patent (U.S. Patent No. 11,135,312) is directed to a process for increasing the proportion of G and C nucleotides to improve the stability of mRNA. Ex. 2 (ECF No. 505-2, at claim 1). Three patents (U.S. Patent Nos. 11,149,278; 11,286,492; and 11,345,920) are directed to a method of treating or preventing an infectious disease by administering an RNA molecule encoded with an antigen and which contains a split Poly (A) tail. Ex. 15 (ECF No. 507-3, ¶¶ 37, 50-51) (sealed version). Two other patents (U.S. Patent Nos. 10,760,070 and 11,667,910) are directed to methods for purifying nucleic acids—specifically linearized DNA and mRNA using a process known as Tangential Flow Filtration (the "TFF Patents"). Pls.' Zydney Opp'n (ECF No. 549-22, at 1) (sealed version).

The final patent (U.S. Patent No. 11,596,686) is directed to the manufacturing of a vaccine against SARS CoV-2 (the "'686" or "COVID Vaccine Patent"). When CureVac initially filed its claims, it asserted three other patents from the same family as the '686 Patent. All these patents claimed, among other things, the use of lipid nanoparticles ("LNP") as a means of delivering the mRNA vaccine. But a nonparty, Acuitas, claimed inventorship and ownership of technology claimed in the patents due to its earlier invention and licensing of the proprietary LNPs. CureVac and Acuitas settled their dispute under terms which required CureVac to dismiss the three other patents in the COVID Vaccine Family and disclaim all the claims in the remaining COVID Vaccine Patent which covered the Acuitas lipids. Stipulation & Mot. Partial Dismissal (ECF No.

311). The '686 Patent is the sole remaining COVID Vaccine Patent. Ex. 2 (ECF No. 491-24, at 19) (sealed version). It is now alleged to be inventive primarily on the basis of Claim 1, which recites elements of a purified mRNA encoded with a particular SARS CoV-2 spike protein.

B. Facts and Procedural History.

On January 5, 2024, the parties filed a Joint Status Report on the Parties' Efforts to Narrow the Case. (ECF No. 193). The stipulation outlined when and how CureVac would narrow the number of asserted claims and when and how BioNTech would narrow the number of prior art-based invalidity arguments it can raise against each claim. Id. Specifically, the agreement states:

> 4. Within 14 days after receipt of CureVac's narrowed set of asserted claims, BioNTech and Pfizer shall identify seven invalidity arguments per such claim, with an "argument" being an anticipation argument[,] . . . an obviousness argument[,] . . . or an obviousness-type double-patenting argument. Each obviousness argument shall be limited to one combination of references, i.e., a combination cannot encompass alternatives. For example, "A in view of B" shall be counted as a single "argument," but "A in view of B or C" or "A in view of B and/or C" shall be counted as two arguments (i.e., "A in view of B" and "A in view of C").
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> 6. Within 14 days after CureVac narrows its set of asserted claims after the close of expert discovery (i.e., by August 29, 2024), BioNTech and Pfizer will narrow their invalidity arguments to no more than four (4) invalidity arguments (as defined above, from among the seven (7) arguments previously identified) per asserted claim.

Id. at 3.

The agreement also outlined how BioNTech could amend invalidity arguments, stating:

> 8. BioNTech and Pfizer may not amend an invalidity argument (as defined above) to add a prior art reference without leave of Court, which shall only be granted upon a showing of good cause. For the avoidance of doubt, the parties' underlying (non)infringement and (in)validity arguments will continue to develop as the case progresses, including during expert discovery, and additional references reflecting the general background knowledge of the person of ordinary skill in the art may be used to further support an invalidity argument (as defined above), but may not be added as an anticipating reference to support an argument under 35 U.S.C. § 102, or added as part of a combination of references to support an obviousness argument under 35 U.S.C. § 103, or an obviousness-type double-patenting argument.

Id. at 3-4.

On December 26, 2024, BioNTech supplemented its Identification of Prior Art Arguments, identifying four prior art-based invalidity arguments for each claim per the stipulation. See Ex. 1 (ECF No. 627-2). This identification narrowed the scope of the invalidity arguments, relying on arguments discussed by witnesses and disclosed during fact and expert discovery. Id. Many of the four arguments per claim combine specific prior art references with the general knowledge of a POSA. Id. BioNTech supports the general knowledge of a POSA in each argument by citing various sources exemplifying what its experts contend was the state of the art at the time the patents were issued. See, e.g., id. at 2 ("[T]he general knowledge of a POSA included but was not limited to, for example, the state of the art of human codon usage and codon optimization as exemplified in, for example, Sambrook and Russell 2001."); id. at 5 (citing up to 16 sources). BioNTech asserts—and CureVac does not dispute—that BioNTech disclosed each of these supporting references during fact and expert discovery. Defs.' Mem. Resp. Pls.' Mot. in Limine No. 4 Preclude "General Background Knowledge" ("BioNTech's No. 4 Opp'n") (ECF No. 690, at 2).

C. Current Motion.

CureVac argues that this court should preclude BioNTech from "relying on obviousness-based invalidity defenses in which they combine specific prior-art references with the 'general background knowledge' of the person of ordinary skill in the art." CureVac's Mot. in Limine No. 4 (and Mem. Supp.) Preclude Defs. Relying on Prior-Art Combination Include "General Background Knowledge" ("CureVac's No. 4 Mem.") (ECF No. 627, at 1). CureVac relies on the Joint Status Report on the Parties' Efforts to Narrow the Case, filed on January 5, 2024. (ECF No. 193). Specifically, CureVac relies on a sentence in the joint stipulation that states: "general background knowledge of the person of ordinary skill in the art . . . may not be added as an

anticipating reference to support an argument under 35 U.S.C. § 102, or added as part of a combination of references to support an obviousness argument under 35 U.S.C. § 103." Id. at 3-4. CureVac takes issue with the fact that BioNTech identified four prior art-based invalidity arguments as agreed upon by the parties but combined each prior art reference with additional references it asserts were within the "general knowledge" of a POSA in its December 26, 2024, identification. CureVac's No. 4 Mem. (ECF No. 627, at 2). CureVac argues that BioNTech's identification of individual references encompassed in the "general knowledge" of a POSA serves as a "flagrant violation" of the above stipulation, and that BioNTech thus expanded the scope of each argument "to an unlimited number of references," unfairly prejudicing CureVac. Id. at 4.

BioNTech responded, arguing that CureVac provided no legal basis for excluding BioNTech's detailed description of "general knowledge" of a POSA. BioNTech's No. 4 Opp'n (ECF No. 690, at 2-3). BioNTech relies on KSR International Co. v. Teleflex Inc., to argue that "a factfinder seeking to determine whether a purported invention would have been obvious to a [POSA] must necessarily assess what general pre-existing knowledge a POSA would have possessed at the time of the purported invention," so "making that determination requires consideration of expert testimony and evidence about that background knowledge." Id. at 1; see id. at 3-4 (citing 550 U.S. 398 (2007)).

BioNTech argues that its identification is consistent with the stipulation in the joint status report, citing the report's acknowledgment that "references reflecting the general background knowledge of the [POSA] may be used to further support an invalidity argument." Id. at 2 (citing (ECF No. 193, at 4)). BioNTech also alleges that the court should deny CureVac's motion because CureVac failed to clearly identify which references it seeks to exclude. Id. at 1, 6. BioNTech asserts that CureVac is not prejudiced by its identification, explaining that its December 26, 2024,

identification actually narrowed its prior art arguments from seven to four as required by the joint stipulation. Id. at 7-8. BioNTech also highlights that it disclosed all of the documents reflecting the state of the prior art during fact and expert discovery, providing CureVac with the opportunity to question witnesses about the prior art and allowing its expert witness to fully respond to the narrowed contentions. Id. at 6-7.

II. STANDARD OF REVIEW

The court may exclude evidence for failure to timely disclose it as a discovery sanction under Rule 37(c). S. States Rack & Fixture, Inc. v. Sherwin-Williams Co., 318 F.3d 592, 595 (4th Cir. 2003); see Fed. R. Civ. P. 26(e)(1)(A) (stating that parties must supplement or correct their disclosures and responses in a timely matter). However, "Rule 37(c)(1) provides two exceptions to the general rule excluding evidence that a party seeks to offer but has failed to properly disclose: (1) when the failure to disclose is 'substantial[ly] justifi[ed],' and (2) when the nondisclosure is 'harmless.'" Id. at 596 (alterations in original).

Courts in the Fourth Circuit generally address these two exceptions together by applying the five-factor test adopted in Southern States. See id. at 596-97; Rambus, Inc. v. Infineon Techs. AG, 145 F. Supp. 2d 721, 726-27 (E.D. Va. 2001); Swimways Corp. & VAP Creative, LTD v. Zuru, Inc., No. 2:13-cv-334, 2014 WL 12573390, at *2-4 (E.D. Va. July 10, 2014). But the court is "not required to tick through each of the Southern States factors. Southern States explains that district courts have 'broad discretion' to decide harmlessness and 'should' – not 'shall' – 'be guided by' the five factors." Wilkins v. Montgomery, 751 F.3d 214, 222 (4th Cir. 2014). Those factors are:

> (1) the surprise to the party against whom the evidence would be offered; (2) the ability of that party to cure the surprise; (3) the extent to which allowing the evidence would disrupt the trial; (4) the importance of the evidence; and (5) the nondisclosing party's explanation for its failure to disclose the evidence.

S. States, 318 F.3d at 597.[1]

III. ANALYSIS

CureVac bases its motion on the language of the joint stipulation that states: "general background knowledge of the person of ordinary skill in the art . . . may not be added as an anticipating reference to support an argument under 35 U.S.C. § 102, or added as part of a combination of references to support an obviousness argument under 35 U.S.C. § 103." (ECF No. 193, at 4). However, CureVac ignores the sentence immediately preceding that statement, which states: "For the avoidance of doubt, the parties' underlying (non)infringement and (in)validity arguments will continue to develop as the case progresses, including during expert discovery, and additional references reflecting the general background knowledge of the person of ordinary skill in the art may be used to further support an invalidity argument (as defined above)." Id. (emphasis added). This sentence allows BioNTech to add supporting references reflecting the background knowledge of a POSA—not standalone references as part of a combination of references to support an obviousness argument. And in its December 26, 2024, identification, BioNTech did not add standalone references, but simply added supporting references that reflected the background knowledge of a POSA as contemplated by the stipulation. Compare Ex. 1 (ECF No. 690-1) (disclosing general background knowledge of a POSA on February 16, 2024, for claims 1-2, 6, 9, 14, and 15, of '312 Patent; for claims 1, 5, 6, 11, 13, 15, 18, and 20 of '278 Patent; for claims 1-3, 6, 20-21, 24-25, and 30 of '492 Patent ; for claims 1-2, 11-16, and 21-28 of '920 Patent; for claims 1-3, 6-7, 9, 11-15, and 23 of '070 Patent; for claims 1-2, 5, 9, 13, 15, 18, 23, and 25-26 of '910 Patent; and for claims 1, 3, 6, 12-14, 17, 19, 23-25, 27, and 30 of '686 Patent), with Ex. 1 (ECF

[1] The Southern States factors mirror a similar test to determine good cause to amend invalidity infringement contentions under Local Patent Rules adopted in the Eastern District of Texas. See Allure Energy Inc. v. Nest Labs, Inc., 84 F. Supp. 3d 538, 540-41 (E.D. Tex. 2015).

No. 627-2) (adding supporting references on December 26, 2024, for generalized knowledge of a POSA for claims 1, 9, and 14-15 of '312 Patent; for claims 15 and 18 of '278 Patent; for claims 6 and 30 of '492 Patent; for claims 2, 12, 14, and 28 of '920 Patent; for claims 2, 7, and 23 of '070 Patent; for claims 5 and 13 of '910 Patent; and for claims 12, 14, and 17 of '686 Patent).

As discussed in analyzing CureVac's Motion to Exclude Testimony from Dr. Rathore, the United States Supreme Court in KSR broadly criticized the rigid approach to obviousness "based on the disclosures of individual prior-art references, with little recourse to the knowledge, creativity, and common sense that an ordinarily skilled artisan would have brought to bear when considering combinations or modifications." Randall Mfg. v. Rea, 733 F.3d 1355, 1362 (Fed. Cir. 2013) (citing KSR Int'l Co., 550 U.S. at 406). In KSR, the Court recognized that a court will often look to "the background knowledge possessed by a person having ordinary skill in the art" to determine obviousness. 550 U.S. at 418. This flexible approach is consistent with other decisions suggesting that the obviousness inquiry "not only permits, but requires, consideration of common knowledge and common sense." Dystar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co., 464 F.3d 1356, 1367 (Fed. Cir. 2006); see also Koninklijke Philips N.V. v. Google LLC, 948 F.3d 1330, 1338 (Fed. Cir. 2020) (affirming obviousness when "the claims would have been obvious over SMIL 1.0 in light of the general knowledge of a skilled artisan."); B/E Aerospace, Inc. v. C&D Zodiac, Inc., 962 F.3d 1373, 1380 (Fed. Cir. 2020) (affirming obviousness when "invocation of common sense was properly accompanied by reasoned analysis and evidentiary support," even when supplying a missing claim limitation with common sense). The challenged documentary evidence is therefore clearly relevant.

Importantly, CureVac has not identified any specific additional references which it claims are not subject to inclusion in the general knowledge of a POSA. Nearly all of the references cited

in CureVac's brief are more than a decade old. CureVac's No. 4 Mem. (ECF No. 627, at 2-3). The parties' stipulation clearly anticipated that these references would change as expert discovery progressed. CureVac cannot claim surprise or undue prejudice from BioNTech's reliance on supporting references that reflect the general knowledge of a POSA that BioNTech disclosed during fact and expert discovery. BioNTech merely developed its arguments "as the case progresse[d]," as contemplated by paragraph eight of the stipulation. Because BioNTech did not violate the stipulation, and because CureVac had ample opportunity to explore in both fact and expert discovery BioNTech's reliance on these supporting references, the court finds no reason to preclude BioNTech from offering any testimony or arguments using the supporting references cited in its December 26, 2024, identification.

IV. CONCLUSION

For the foregoing reasons, the court DENIES CureVac's Motion in Limine No. 4, (ECF No. 626).

IT IS SO ORDERED.

/s/
Douglas E. Miller
United States Magistrate Judge

DOUGLAS E. MILLER
UNITED STATES MAGISTRATE JUDGE

Norfolk, Virginia
February 24, 2025